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Hetero Labs Limited Unit-V, and
Hetero Labs Ltd.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

AXSOME MALTA LTD. and ASXOME
THERAPEUTICS, INC.,

Plaintiffs,

v.

ALKEM LABORATORIES LTD.,
AUROBINDO PHARMA USA, INC.,
HETERO USA INC., HETERO LABS
LIMITED UNIT-V, HETERO LABS LTD.,
HIKMA PHARMACEUTICALS USA, INC.,
SANDOZ INC., and UNICHEM
LABORATORIES LTD.,

Defendants.

Civil Action No. 2:23-cv-20354-MCA-JBC

**DEFENDANTS HETERO USA INC., HETERO LABS LIMITED UNIT-V, AND
HETERO LABS LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND
COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT**

Defendants Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd.
(collectively, "Hetero"), by and through their undersigned counsel, file this Answer, Affirmative
Defenses, and Counterclaims to Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc.'s
(collectively, "Axsome" or "Plaintiffs") Complaint, and state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Hetero denies all allegations in Axsome's Complaint except those specifically admitted below.

Nature of the Action

1. This complaint is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, et seq., arising from Defendants' submission of their respective Abbreviated New Drug Application ("ANDA") Nos. 218722 ("Alkem's ANDA"), 218725 ("Aurobindo's ANDA"), 218654 ("Hetero's ANDA"), 218016 ("Hikma's ANDA"), 218610 ("Sandoz's ANDA"), and 218761 ("Unichem's ANDA"), with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Axsome's solriamfetol oral tablets drug products prior to the expiration of one or more of United States Patent Nos. 8,440,715 ("the '715 patent"), 8,877,806 ("the '806 patent"), 9,604,917 ("the '917 patent"), 10,351,517 ("the '517 patent"), 10,195,151 ("the '151 patent"), 10,512,609 ("the '609 patent"), 11,439,597 ("the '597 patent"), 10,912,754 ("the '754 patent"), 10,959,976 ("the '976 patent"), 11,160,779 ("the '779 patent"), 10,940,133 ("the '133 patent"), 11,560,354 ("the '354 patent"), and 11,648,232 ("the '232 patent") (collectively, "the patents-in-suit"). Axsome is the owner of or exclusive licensee for all substantial rights in the patents-in-suit.

ANSWER: Hetero admits that Axsome filed a civil action alleging Hetero infringed U.S. Patent Nos. 8,440,715 ("the '715 patent"), 10,195,151 ("the '151 patent"), 10,512,609 ("the '609 patent"), 11,439,597 ("the '597 patent"), 10,912,754 ("the '754 patent"), 10,959,976 ("the '976 patent"), 11,160,779 ("the '779 patent"), 10,940,133 ("the '133 patent"), 11,560,354 ("the '354 patent"), and 11,648,232 ("the '232 patent") (collectively, "the patents-in-suit") under the patent laws of the United States, Title 35, United States Code. Hetero admits that it had filed an Abbreviated New Drug Application ("ANDA") No. 218654 to the U.S. Food and Drug Administration ("FDA"). Except as expressly admitted, Hetero is without knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 1, and on that basis denies these allegations.

The Parties

2. Plaintiff Axsome is a biopharmaceutical company focused on developing novel therapies for central nervous system (“CNS”) conditions that have limited treatment options. One such therapy, Sunosi[®] (solriamfetol) oral tablets, is a dopamine and norepinephrine reuptake inhibitor (“DNRI”) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

ANSWER: Hetero admits that Sunosi[®] is approved by FDA as a dopamine and norepinephrine reuptake inhibitor (“DNRI”) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Except as expressly admitted, Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2, and on that basis denies these allegations.

3. Axsome Malta Ltd. is a corporation organized and existing under the laws of the Republic of Malta, having a principal place of business at 78 Mill Street, Zone 5, Central Business District, Qormi, CBD 5090, Malta.

ANSWER: Paragraph 3 contains legal conclusions to which no answer is required. To the extent that Hetero is required to answer, on information and belief, Hetero admits Axsome Malta Ltd. is a corporation organized and existing under the laws of the Republic of Malta, having a principal place of business at 78 Mill Street, Zone 5, Central Business District, Qormi, CBD 5090, Malta. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 3, and on that basis denies any and all remaining allegations of Paragraph 3.

4. Axsome Therapeutics, Inc., is a corporation organized and existing under the laws of Delaware, having a principal place of business at One World Trade Center, 22nd Floor, New York, New York 10007.

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent that Hetero is required to answer, on information and belief, Hetero admits Axsome Therapeutics, Inc., is a corporation organized and existing under the laws of Delaware, having a

principal place of business at One World Trade Center, 22nd Floor, New York, New York 10007.

Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 4, and on that basis denies any and all remaining allegations of Paragraph 4.

5. On information and belief, Defendant Alkem is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, Maharashtra, India.

ANSWER: The allegations in Paragraph 5 are not directed to Hetero, so no response is required. To the extent a response is required, Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 5, and on that basis denies these allegations.

6. On information and belief, Defendant Aurobindo is a corporation organized and existing under the laws of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER: The allegations in Paragraph 6 are not directed to Hetero, so no response is required. To the extent a response is required, Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 6, and on that basis denies these allegations.

7. On information and belief, Defendant Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

ANSWER: Hetero admits that Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

8. On information and belief, Defendant Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar – 509301, Andhra Pradesh, India.

ANSWER: Hetero admits that Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar – 509301, Andhra Pradesh, India.

9. On information and belief, Defendant Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

ANSWER: Hetero admits that Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

10. On information and belief, Defendant Hikma is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

ANSWER: The allegations in Paragraph 10 are not directed to Hetero, so no response is required. To the extent a response is required, Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 10, and on that basis denies these allegations.

11. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado, having its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

ANSWER: The allegations in Paragraph 11 are not directed to Hetero, so no response is required. To the extent a response is required, Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 11, and on that basis denies these allegations.

12. On information and belief, Defendant Unichem is a corporation organized and existing under the laws of India, having its principal place of business at Centre of Excellence, Plot No. 12 to 14, Pilerne Industrial Estate, Pilerne, Bardez, Goa 403 511, India.

ANSWER: The allegations in Paragraph 12 are not directed to Hetero, so no response is required. To the extent a response is required, Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 12, and on that basis denies these allegations.

13. On information and belief, Defendants are all pharmaceutical companies that formulate, manufacture, package, and market generic drug products for distribution in the District of New Jersey and throughout the United States.

ANSWER: Paragraph 13 contains legal conclusions to which no response is required. To the extent an answer is required, Paragraph 13 is directed to all Defendants, and Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 13, and on that basis denies any and all remaining allegations of Paragraph 13.

The Patents-in-Suit

14. On May 14, 2013, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’715 patent, entitled, “Treatment of Sleep-wake Disorders.” The face of the ’715 patent identifies Abdallah Ahnaou, Wilhelmus H. L. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors. A copy of the ’715 patent is attached hereto as Exhibit A.

ANSWER: Hetero admits that the ’715 patent is titled “Treatment of Sleep-wake Disorders.” Hetero admits that the face of the ’715 patent identifies Abdallah Ahnaou, Wilhelmus H. I. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors, and that the ’715 patent was issued by the USPTO on or about May 14, 2013. What appears to be an uncertified copy of the ’715 patent was attached to Plaintiffs’ Complaint as Exhibit A. Hetero denies the remaining allegations in Paragraph 14.

15. On November 4, 2014, the USPTO duly and lawfully issued the ’806 patent, entitled, “Treatment of Sleep-wake Disorders.” The face of the ’806 patent identifies Abdallah Ahnaou, Wilhelmus H. L. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors. A copy of the ’806 patent is attached hereto as Exhibit B.

ANSWER: Hetero admits that the '806 patent is titled "Treatment of Sleep-wake Disorders." Hetero admits that the face of the '806 patent identifies Abdallah Ahnaou, Wilhelmus H. I. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors, and that the '806 patent was issued by the USPTO on or about November 4, 2014. What appears to be an uncertified copy of the '806 patent was attached to Plaintiffs' Complaint as Exhibit B. Hetero denies the remaining allegations in Paragraph 15.

16. On March 28, 2017, the USPTO duly and lawfully issued the '917 patent, entitled, "Treatment of Sleep-wake Disorders." The face of the '917 patent identifies Abdallah Ahnaou, Wilhelmus H. L. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors. A copy of the '917 patent is attached hereto as Exhibit C.

ANSWER: Hetero admits that the '917 patent is titled "Treatment of Sleep-wake Disorders." Hetero admits that the face of the '917 patent identifies Abdallah Ahnaou, Wilhelmus H. I. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors, and that the '917 patent was issued by the USPTO on or about March 28, 2017. What appears to be an uncertified copy of the '917 patent was attached to Plaintiffs' Complaint as Exhibit C. Hetero denies the remaining allegations in Paragraph 16.

17. On July 16, 2019, the USPTO duly and lawfully issued the '517 patent, entitled, "Treatment of Sleep-wake Disorders." The face of the '517 patent identifies Abdallah Ahnaou, Wilhelmus H. L. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors. A copy of the '517 patent is attached hereto as Exhibit D.

ANSWER: Hetero admits that the '517 patent is titled "Treatment of Sleep-wake Disorders." Hetero admits that the face of the '517 patent identifies Abdallah Ahnaou, Wilhelmus H. I. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors, and that the '517 patent was issued by the USPTO on or about July 16, 2019. What appears to be an uncertified copy of the '517 patent was attached to Plaintiffs' Complaint as Exhibit D. Hetero denies the remaining allegations in Paragraph 17.

18. On February 5, 2019, the USPTO duly and lawfully issued the '151 patent, entitled, "Formulations of (R)-2-amino-3-phenylpropyl carbamate." The face of the '151 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors. A copy of the '151 patent is attached hereto as Exhibit E.

ANSWER: Hetero admits that the '151 patent is titled "Formulations of (R)-2-amino-3-phenylpropyl carbamate." Hetero admits that the face of the '151 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors, and that the '151 patent was issued by the USPTO on or about February 5, 2019. What appears to be an uncertified copy of the '151 patent was attached to Plaintiffs' Complaint as Exhibit E. Hetero denies the remaining allegations in Paragraph 18.

19. On December 24, 2019, the USPTO duly and lawfully issued the '609 patent, entitled, "Formulations of (R)-2-amino-3-phenylpropyl carbamate." The face of the '609 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors. A copy of the '609 patent is attached hereto as Exhibit F.

ANSWER: Hetero admits that the '609 patent is titled "Formulations of (R)-2-amino-3-phenylpropyl carbamate." Hetero admits that the face of the '609 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors, and that the '609 patent was issued by the USPTO on or about December 24, 2019. What appears to be an uncertified copy of the '609 patent was attached to Plaintiffs' Complaint as Exhibit F. Hetero denies the remaining allegations in Paragraph 19.

20. On September 13, 2022, the USPTO duly and lawfully issued the '597 patent, entitled, "Formulations of (R)-2-amino-3-phenylpropyl carbamate." The face of the '597 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors. A copy of the '597 patent is attached hereto as Exhibit G.

ANSWER: Hetero admits that the '597 patent is titled "Formulations of (R)-2-amino-3-phenylpropyl carbamate." Hetero admits that the face of the '597 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors, and that the '597 patent was issued by the USPTO on or about September 13, 2022. What appears to be an uncertified copy of the '597

patent was attached to Plaintiffs' Complaint as Exhibit G. Hetero denies the remaining allegations in Paragraph 20.

21. On February 9, 2021, the USPTO duly and lawfully issued the '754 patent, entitled, "Methods and Compositions for Treating Excessive Sleepiness." The face of the '754 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors. A copy of the '754 patent is attached hereto as Exhibit H.

ANSWER: Hetero admits that the '754 patent is titled "Methods and Compositions for Treating Excessive Sleepiness." Hetero admits that the face of the '754 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors, and that the '754 patent was issued by the USPTO on or about February 9, 2021. What appears to be an uncertified copy of the '754 patent was attached to Plaintiffs' Complaint as Exhibit H. Hetero denies the remaining allegations in Paragraph 21.

22. On March 30, 2021, the USPTO duly and lawfully issued the '976 patent, entitled, "Methods and Compositions for Treating Excessive Sleepiness." The face of the '976 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors. A copy of the '976 patent is attached hereto as Exhibit I.

ANSWER: Hetero admits that the '976 patent is titled "Methods and Compositions for Treating Excessive Sleepiness." Hetero admits that the face of the '976 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors, and that the '976 patent was issued by the USPTO on or about March 30, 2021. What appears to be an uncertified copy of the '976 patent was attached to Plaintiffs' Complaint as Exhibit I. Hetero denies the remaining allegations in Paragraph 22.

23. On November 2, 2021, the USPTO duly and lawfully issued the '779 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '779 patent identifies Katayoun Zomorodi as the inventor. A copy of the '779 patent is attached hereto as Exhibit J.

ANSWER: Hetero admits that the '779 patent is titled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." Hetero admits that the face of the '779 patent identifies Katayoun Zomorodi as the inventor, and that the '779 patent was issued by the USPTO on or about November 2, 2021. What appears to be an uncertified copy of the '779 patent was attached to Plaintiffs' Complaint as Exhibit J. Hetero denies the remaining allegations in Paragraph 23.

24. On March 9, 2021, the USPTO duly and lawfully issued the '133 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '133 patent identifies Katayoun Zomorodi as the inventor. A copy of the '133 patent is attached hereto as Exhibit K.

ANSWER: Hetero admits that the '133 patent is titled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." Hetero admits that the face of the '133 patent identifies Katayoun Zomorodi as the inventor, and that the '133 patent was issued by the USPTO on or about March 9, 2021. What appears to be an uncertified copy of the '133 patent was attached to Plaintiffs' Complaint as Exhibit K. Hetero denies the remaining allegations in Paragraph 24.

25. On January 24, 2023, the USPTO duly and lawfully issued the '354 patent, entitled, "Compositions comprising (R)-2-amino-3-phenylpropyl carbamate and uses thereof." The face of the '354 patent identifies Fionn Hurley as the inventor. A copy of the '354 patent is attached hereto as Exhibit L.

ANSWER: Hetero admits that the '354 patent is titled "Compositions comprising (R)-2-amino-3-phenylpropyl carbamate and uses thereof." Hetero admits that the face of the '354 patent identifies Fionn Hurley as the inventor, and that the '354 patent was issued by the USPTO on or about January 24, 2023. What appears to be an uncertified copy of the '354 patent was attached to Plaintiffs' Complaint as Exhibit L. Hetero denies the remaining allegations in Paragraph 25.

26. On May 16, 2023, the USPTO duly and lawfully issued the '232 patent, entitled, "Methods and Compositions for Treating Excessive Sleepiness." The face of the '232 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors. A copy of the '232 patent is attached hereto as Exhibit M.

ANSWER: Hetero admits that the '232 patent is titled "Methods and Compositions for Treating Excessive Sleepiness." Hetero admits that the face of the '232 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors, and that the '232 patent was issued by the USPTO on or about May 16, 2023. What appears to be an uncertified copy of the '232 patent was attached to Plaintiffs' Complaint as Exhibit M. Hetero denies the remaining allegations in Paragraph 26.

The Sunosi® Drug Product

27. Axsome holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base ("NDA No. 211230"), which is sold under the trade name Sunosi®. Sunosi® is a DNRI indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. The claims of the patents-in-suit cover, inter alia, solriamfetol pharmaceutical compositions and methods of using Sunosi® to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. Hetero admits that the FDA publication, the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), lists Axsome Malta Ltd. as the holder of NDA No. 211230 for Sunosi® (solriamfetol hydrochloride) in oral tablets, Eq. 75 mg base and Eq. 150 mg base. Hetero admits that Sunosi® is approved by FDA as a DNRI indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Except as expressly admitted, Hetero is without knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 27, and on that basis denies these allegations.

28. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to Sunosi®.

ANSWER: Hetero admits that, according to the Orange Book, the patents-in-suit are listed in connection with Sunosi® (solriamfetol hydrochloride) in oral tablets, Eq. 75 mg base and Eq. 150 mg base. Except as expressly admitted, Hetero is without knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28, and on that basis denies these allegations.

Jurisdiction and Venue: Alkem

Paragraphs 29 to 37 pertain to Defendant Alkem Laboratories Ltd. (“Alkem”). Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Jurisdiction and Venue: Aurobindo

Paragraphs 38 to 46 pertain to Defendant Aurobindo Pharma USA, Inc. (“Aurobindo”). Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Jurisdiction and Venue: Hetero

47. This Court has jurisdiction over the subject matter of Counts XIX through XXVIII against Hetero pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest subject matter jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 47.

48. As set forth below, the Court has personal jurisdiction over each of Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. by virtue of, *inter alia*, their systematic and continuous contacts with the State of New Jersey.

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 48.

49. On information and belief, Hetero purposefully has conducted and continues to conduct business in this Judicial District.

ANSWER: To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 49.

50. On information and belief, Hetero is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER: Hetero Labs Limited Unit-V and Hetero Labs Ltd. admit that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers in the United States. Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 50.

51. On information and belief, this Judicial District will be a destination for the generic version of Axsome's solriamfetol oral tablets drug products for which Hetero seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218654 ("Hetero's Proposed Product").

ANSWER: Hetero admits that it seeks regulatory approval from the FDA for ANDA No. 218654. The content of Hetero's ANDA speaks for itself. Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 51.

52. This Court has personal jurisdiction over Hetero Labs Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the

State of New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Hetero USA Inc., a company with a regular and established physical place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Hetero USA Inc.

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero Labs Ltd. admits that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers in the United States. Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 52.

53. This Court has personal jurisdiction over Hetero Labs Limited Unit-V because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Hetero USA Inc., a company with a regular and established physical place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Hetero USA Inc.

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero Labs Limited Unit-V admits that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers in the United States. Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 53.

54. This Court has personal jurisdiction over Hetero USA Inc. because, *inter alia*, on information and belief, Hetero USA Inc. maintains a regular and established, physical place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

ANSWER: Hetero USA Inc. admits that it has a physical place of business at 1035 Centennial Avenue, Piscataway, NJ 08854. Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 54.

55. On information and belief, Hetero USA Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400362826.

ANSWER: Admitted.

56. On information and belief, Hetero USA Inc. will work in concert with Hetero Labs Limited Unit-V and/or Hetero Labs Ltd. toward the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Hetero's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 56.

57. Hetero has consented to personal jurisdiction in this Court in recent actions arising out of its ANDA submissions and has filed counterclaims in such cases. *See, e.g., Celgene Corporation v. Annora Pharma Private Limited, et al.*, C.A. No. 3-18-cv-11220 (D.N.J.) (Hetero USA Inc.); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 2-19-cv-15449 (SDW)(LDW) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 2-19-cv-05797 (ES)(MAH) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 2-18-cv-17463 (SDW)(LDW) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 2-18-cv-14111 (ES)(MAH) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 2-17-cv-03387 (ES)(MAH) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Otsuka Pharm. Co., Ltd. v. Hetero Drugs Ltd., et al.*, Civil Action No. 1-15-cv-00161 (JBS)(KMW) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd.); *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, Civil Action No. 1-16-cv-02442 (RMB)(JS) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd.); and *BTG*

Int'l Ltd., et al. v. Actavis Labs. FL, Inc., et al., Civil Action No. 2-15-cv-05909 (KM)(JBC) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V). Hetero has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Prior consent to personal jurisdiction in this Court has no bearing on this action. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 57.

58. In the alternative, this Court has personal jurisdiction over Hetero Labs Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Axsome's claims arise under federal law; (b) Hetero Labs Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Labs Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Labs Ltd. satisfies due process.

ANSWER: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 58.

59. In the alternative, this Court has personal jurisdiction over Hetero Labs Limited Unit-V because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Axsome's claims arise under federal law; (b) Hetero Labs Limited Unit-V is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Labs Limited Unit-V has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Labs Limited Unit-V satisfies due process.

ANSWER: Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal

jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 59.

60. At least because, on information and belief, Hetero Labs Ltd. and Hetero Labs Limited Unit-V are foreign companies, venue is proper in this Judicial District with respect to Hetero Labs Ltd. and Hetero Labs Limited Unit-V pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b). Also, for at least the reasons set forth above in Paragraphs 49-57, venue is proper in this Judicial District as to Hetero USA Inc. pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

ANSWER: Paragraph 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest venue in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 60.

Jurisdiction and Venue: Hikma

Paragraphs 61 to 69 pertain to Defendant Hikma Pharmaceuticals USA Inc. (“Hikma”). Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Jurisdiction and Venue: Sandoz

Paragraphs 70 to 78 pertain to Defendant Sandoz Inc. (“Sandoz”). Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Jurisdiction and Venue: Unichem

Paragraphs 79 to 86 pertain to Defendant Unichem Laboratories Ltd. (“Unichem”). Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Acts Giving Rise To Counts I-X Against Alkem

Paragraphs 87 to 91 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Acts Giving Rise To Counts XI-XVIII Against Aurobindo

Paragraphs 92 to 96 pertain to Aurobindo. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Acts Giving Rise To Counts XIX-XXVIII Against Hetero

97. Pursuant to Section 505 of the FFDCA, Hetero submitted ANDA No. 218654 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Hetero's Proposed Product, before certain patents-in-suit expire.

ANSWER: Hetero admits that it seeks regulatory approval from the FDA for ANDA No. 218654. The content of Hetero's ANDA speaks for itself. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 97.

98. No earlier than August 15, 2023, Hetero sent written notice of a Paragraph IV Certification ("Hetero's Notice Letter") to Axsome. According to Hetero's Notice Letter, Hetero submitted an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

ANSWER: Hetero admits that it sent a notice letter to Axsome, which included notice that Hetero is seeking approval for Hetero's Proposed Product prior to the expiration of certain patents listed in the Orange Book with respect to Sunosi®. The content of the Hetero's Notice Letter speaks for itself. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 98.

99. Hetero's Notice Letter alleges that the claims of certain patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Hetero's ANDA.

ANSWER: Hetero admits that it sent a notice letter to Axsome, which included notice that Hetero is seeking approval for Hetero's Proposed Product prior to the expiration of certain patents listed in the Orange Book with respect to Sunosi®. The content of the Hetero's Notice Letter speaks for itself. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 99.

100. On information and belief, in connection with the submission of its ANDA as described above, Hetero provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Hetero's Paragraph IV Certification"), alleging that the claims of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '754 patent, the '976 patent, the '779 patent, the '133 patent, the '354 patent, and the '232 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Hetero's ANDA.

ANSWER: Hetero admits that it had provided a Paragraph IV Certification to the FDA in connection with the submission of its ANDA No. 218654. The content of Hetero's Paragraph IV Certification speaks for itself. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 100.

101. On information and belief, following FDA approval of Hetero's ANDA, Hetero will make, use, offer to sell, or sell Hetero's Proposed Product throughout the United States, or import such a generic product into the United States.

ANSWER: Hetero's ANDA has not yet been tentatively or finally approved by FDA and the allegations of Paragraph 101 are wholly speculative. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 101.

Acts Giving Rise To Counts XXIX-XXXVIII Against Hikma

Paragraphs 102 to 106 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Acts Giving Rise To Counts XXXIX-XLVIII Against Sandoz

Paragraphs 107 to 111 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Acts Giving Rise To Counts XLIX-LXI Against Unichem

Paragraphs 112 to 116 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count I: Infringement of the '715 Patent by Alkem

Paragraphs 117 to 125 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count II: Infringement of the '151 Patent by Alkem

Paragraphs 126 to 134 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count III: Infringement of the '609 Patent by Alkem

Paragraphs 135 to 143 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count IV: Infringement of the '597 Patent by Alkem

Paragraphs 144 to 152 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count V: Infringement of the '754 Patent by Alkem

Paragraphs 153 to 161 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count VI: Infringement of the '976 Patent by Alkem

Paragraphs 162 to 170 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count VII: Infringement of the '779 Patent by Alkem

Paragraphs 171 to 179 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count VIII: Infringement of the '133 Patent by Alkem

Paragraphs 180 to 188 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count IX: Infringement of the '354 Patent by Alkem

Paragraphs 189 to 197 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count X: Infringement of the '232 Patent by Alkem

Paragraphs 198 to 206 pertain to Alkem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XI: Infringement of the '715 Patent by Aurobindo

Paragraphs 207 to 215 pertain to Aurobindo. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XII: Infringement of the '151 Patent by Aurobindo

Paragraphs 216 to 224 pertain to Aurobindo. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XIII: Infringement of the '609 Patent by Aurobindo

Paragraphs 225 to 233 pertain to Aurobindo. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XIV: Infringement of the '597 Patent by Aurobindo

Paragraphs 234 to 242 pertain to Aurobindo. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XV: Infringement of the '976 Patent by Aurobindo

Paragraphs 243 to 251 pertain to Aurobindo. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XVI: Infringement of the '779 Patent by Aurobindo

Paragraphs 252 to 260 pertain to Aurobindo. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XVII: Infringement of the '354 Patent by Aurobindo

Paragraphs 261 to 269 pertain to Aurobindo. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XVIII: Infringement of the '232 Patent by Aurobindo

Paragraphs 270 to 278 pertain to Aurobindo. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XIX: Infringement of the '715 Patent by Hetero

279. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

280. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '715 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 280 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 280.

281. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '715 patent.

ANSWER: Paragraph 281 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 281.

282. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '715 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 282 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 282.

283. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '715 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '715 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 283 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 283.

284. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '715 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '715 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 284 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 284.

285. Failure to enjoin Hetero's infringement of the '715 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Paragraph 285 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 285.

286. Axsome does not have an adequate remedy at law.

ANSWER: Paragraph 286 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 286.

287. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 287 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 287.

Count XX: Infringement of the '151 Patent by Hetero

288. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

289. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '151 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 289 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 289.

290. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '151 patent.

ANSWER: Paragraph 290 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 290.

291. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '151 patent under 35 U.S.C. § 271(a),

including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 291 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 291.

292. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '151 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '151 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 292 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 292.

293. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '151 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '151 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 293 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 293.

294. Failure to enjoin Hetero's infringement of the '151 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Paragraph 294 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 294.

295. Axsome does not have an adequate remedy at law.

ANSWER: Paragraph 295 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 295.

296. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 296 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 296.

Count XXI: Infringement of the '609 Patent by Hetero

297. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

298. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '609 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 298 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 298.

299. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '609 patent.

ANSWER: Paragraph 299 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 299.

300. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '609 patent under 35 U.S.C. § 271(a),

including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 300 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 300.

301. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '609 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '609 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 301 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 301.

302. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '609 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '609 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 302 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 302.

303. Failure to enjoin Hetero's infringement of the '609 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Paragraph 303 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 303.

304. Axsome does not have an adequate remedy at law.

ANSWER: Paragraph 304 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 304.

305. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 305 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 305.

Count XXII: Infringement of the '597 Patent by Hetero

306. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

307. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '597 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 307 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 307.

308. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '597 patent.

ANSWER: Paragraph 308 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 308.

309. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '597 patent under 35 U.S.C. § 271(a),

including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 309 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 309.

310. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '597 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '597 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 310 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 310.

311. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '597 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '597 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 311 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 311.

312. Failure to enjoin Hetero's infringement of the '597 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Paragraph 312 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 312.

313. Axsome does not have an adequate remedy at law.

ANSWER: Paragraph 313 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 313.

314. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 314 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 314.

Count XXIII: Infringement of the '754 Patent by Hetero

315. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

316. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '754 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 316 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 316.

317. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '754 patent.

ANSWER: Paragraph 317 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 317.

318. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '754 patent under 35 U.S.C. § 271(a),

including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 318 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 318.

319. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '754 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '754 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 319 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 319.

320. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '754 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '754 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 320 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 320.

321. Failure to enjoin Hetero's infringement of the '754 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Paragraph 321 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 321.

322. Axsome does not have an adequate remedy at law.

ANSWER: Paragraph 322 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 322.

323. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 323 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 323.

Count XXIV: Infringement of the '976 Patent by Hetero

324. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

325. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '976 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 325 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 325.

326. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '976 patent.

ANSWER: Paragraph 326 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 326.

327. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '976 patent under 35 U.S.C. § 271(a),

including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 327 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 327.

328. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '976 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '976 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 328 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 328.

329. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '976 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '976 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 329 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 329.

330. Failure to enjoin Hetero's infringement of the '976 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Paragraph 330 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 330.

331. Axsome does not have an adequate remedy at law.

ANSWER: Paragraph 331 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 331.

332. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 332 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 332.

Count XXV: Infringement of the '779 Patent by Hetero

333. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

334. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '779 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 334 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 334.

335. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '779 patent.

ANSWER: Paragraph 335 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 335.

336. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '779 patent under 35 U.S.C. § 271(a),

including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 336 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 336.

337. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '779 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '779 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 337 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 337.

338. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '779 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '779 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 338 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 338.

339. Failure to enjoin Hetero's infringement of the '779 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Paragraph 339 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 339.

340. Axsome does not have an adequate remedy at law.

ANSWER: Paragraph 340 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 340.

341. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 341 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 341.

Count XXVI: Infringement of the '133 Patent by Hetero

342. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

343. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '133 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 343 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 343.

344. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '133 patent.

ANSWER: Paragraph 344 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 344.

345. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '133 patent under 35 U.S.C. § 271(a),

including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 345 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 345.

346. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '133 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '133 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 346 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 346.

347. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '133 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '133 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 347 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 347.

348. Failure to enjoin Hetero's infringement of the '133 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Paragraph 348 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 348.

349. Axsome does not have an adequate remedy at law.

ANSWER: Paragraph 349 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 349.

350. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 350 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 350.

Count XXVII: Infringement of the '354 Patent by Hetero

351. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

352. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '354 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 352 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 352.

353. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '354 patent.

ANSWER: Paragraph 353 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 353.

354. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '354 patent under 35 U.S.C. § 271(a),

including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 354 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 354.

355. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '354 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '354 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 355 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 355.

356. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '354 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '354 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 356 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 356.

357. Failure to enjoin Hetero's infringement of the '354 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Paragraph 357 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 357.

358. Axsome does not have an adequate remedy at law.

ANSWER: Paragraph 358 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 358.

359. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 359 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 359.

Count XXVIII: Infringement of the '232 Patent by Hetero

360. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

361. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '232 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 361 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 361.

362. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '232 patent.

ANSWER: Paragraph 362 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 362.

363. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '232 patent under 35 U.S.C. § 271(a),

including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 363 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 363.

364. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '232 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '232 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 364 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 364.

365. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '232 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '232 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 365 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 365.

366. Failure to enjoin Hetero's infringement of the '232 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Paragraph 366 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 366.

367. Axsome does not have an adequate remedy at law.

ANSWER: Paragraph 367 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 367.

368. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 368 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 368.

Count XXIX: Infringement of the '715 Patent by Hikma

Paragraphs 369 to 377 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XXX: Infringement of the '151 Patent by Hikma

Paragraphs 378 to 386 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XXXI: Infringement of the '609 Patent by Hikma

Paragraphs 387 to 395 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XXXII: Infringement of the '597 Patent by Hikma

Paragraphs 396 to 404 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XXXIII: Infringement of the '754 Patent by Hikma

Paragraphs 405 to 413 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XXXIV: Infringement of the '976 Patent by Hikma

Paragraphs 414 to 422 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XXXV: Infringement of the '779 Patent by Hikma

Paragraphs 423 to 431 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XXXVI: Infringement of the '133 Patent by Hikma

Paragraphs 432 to 440 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XXXVII: Infringement of the '354 Patent by Hikma

Paragraphs 441 to 449 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XXXVIII: Infringement of the '232 Patent by Hikma

Paragraphs 450 to 458 pertain to Hikma. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XXXIX: Infringement of the '715 Patent by Sandoz

Paragraphs 459 to 467 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XL: Infringement of the '151 Patent by Sandoz

Paragraphs 468 to 476 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XLI: Infringement of the '609 Patent by Sandoz

Paragraphs 477 to 485 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XLII: Infringement of the '597 Patent by Sandoz

Paragraphs 486 to 494 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XLIII: Infringement of the '754 Patent by Sandoz

Paragraphs 495 to 503 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XLIV: Infringement of the '976 Patent by Sandoz

Paragraphs 504 to 512 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XLV: Infringement of the '779 Patent by Sandoz

Paragraphs 513 to 521 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XLVI: Infringement of the '133 Patent by Sandoz

Paragraphs 522 to 530 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XLVII: Infringement of the '354 Patent by Sandoz

Paragraphs 531 to 539 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XLVIII: Infringement of the '232 Patent by Sandoz

Paragraphs 540 to 548 pertain to Sandoz. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count XLIX: Infringement of the '715 Patent by Unichem

Paragraphs 549 to 557 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count L: Infringement of the '151 Patent by Unichem

Paragraphs 558 to 566 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count LI: Infringement of the '609 Patent by Unichem

Paragraphs 567 to 575 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count LII: Infringement of the '597 Patent by Unichem

Paragraphs 576 to 584 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count LIII: Infringement of the '754 Patent by Unichem

Paragraphs 585 to 593 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count LIV: Infringement of the '976 Patent by Unichem

Paragraphs 594 to 602 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count LV: Infringement of the '779 Patent by Unichem

Paragraphs 603 to 611 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count LVI: Infringement of the '133 Patent by Unichem

Paragraphs 612 to 620 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count LVII: Infringement of the '354 Patent by Unichem

Paragraphs 621 to 629 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count LVIII: Infringement of the '232 Patent by Unichem

Paragraphs 630 to 638 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore,

denies these allegations.

Count LIX: Infringement of the '806 Patent by Unichem

Paragraphs 639 to 647 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count LX: Infringement of the '917 Patent by Unichem

Paragraphs 648 to 656 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

Count LXI: Infringement of the '517 Patent by Unichem

Paragraphs 657 to 665 pertain to Unichem. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in these paragraphs, and therefore, denies these allegations.

AXSOME'S PRAYER FOR RELIEF AGAINST HETERO

All allegations in Axsome's Complaint that are not expressly admitted by Hetero are denied. Hetero denies that Axsome is entitled to any of the relief sought in its Prayer for Relief Against Hetero.

HETERO'S AFFIRMATIVE DEFENSES

Without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not expressly admitted, Hetero asserts the following Affirmative Defenses to Axsome's Complaint without assuming the burden of proof on any defense that would otherwise rest on Axsome. Hetero reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Hetero's ANDA No. 218654 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the patents-in-suit.

SECOND DEFENSE

Each of the claims of each of the patents-in-suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, or for failure to satisfy other judicially-created bases for invalidation or unenforceability, for example, for at least the reasons set forth in Hetero's Notice Letter.

THIRD DEFENSE

Axsome's Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or willful infringement. Hetero's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

RESERVATION OF DEFENSES

Hetero reserves any and all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

HETERO'S COUNTERCLAIMS

Defendants Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. (collectively, "Hetero"), by and through their undersigned counsel, plead the following counterclaims against Plaintiffs/Counterclaim Defendants Axsome Malta Ltd. and Axsome Therapeutics, Inc.'s (collectively, "Axsome" or "Plaintiffs"):

PARTIES

1. Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

2. Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar – 509301, Andhra Pradesh, India.

3. Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

4. On information and belief, Axsome Malta Ltd. is a corporation organized and existing under the laws of the Republic of Malta, having a principal place of business at 78 Mill Street, Zone 5, Central Business District, Qormi, CBD 5090, Malta.

5. On information and belief, Axsome Therapeutics, Inc., is a corporation organized and existing under the laws of Delaware, having a principal place of business at One World Trade Center, 22nd Floor, New York, New York 10007.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; based on an actual controversy between Hetero, on the one hand, and Axsome on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

7. This Court has personal jurisdiction over Axsome because, *inter alia*, Axsome subjected itself to the jurisdiction of this Court by filing its Complaint here.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b), and/or by Axsome's choice of forum.

FACTUAL BACKGROUND

9. On information and belief, and based on the allegations in the Complaint, Axsome is the holder of New Drug Application ("NDA") No. 211230 for solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base, which is sold under trade name Sunosi®.

10. On information and belief, and based on the allegations in the Complaint, Axsome caused the Food and Drug Administration ("FDA") to list U.S. Patent Nos. 8,440,715 ("the '715 patent"), 10,195,151 ("the '151 patent"), 10,512,609 ("the '609 patent"), 11,439,597 ("the '597 patent"), 10,912,754 ("the '754 patent"), 10,959,976 ("the '976 patent"), 11,160,779 ("the '779 patent"), 10,940,133 ("the '133 patent"), 11,560,354 ("the '354 patent"), and 11,648,232 ("the '232 patent") (collectively, "the Asserted Patents") in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 211230.

11. The '715 patent lists the title as "Treatment of Sleep-wake Disorders," and the issue date as May 14, 2013.

12. The '151 patent lists the title as "Formulations of (R)-2-amino-3-phenylpropyl carbamate," and the issue date as February 5, 2019.

13. The '609 patent lists the title as "Formulations of (R)-2-amino-3-phenylpropyl carbamate," and the issue date as December 24, 2019.

14. The '597 patent lists the title as "Formulations of (R)-2-amino-3-phenylpropyl carbamate," and the issue date as September 13, 2022.

15. The '754 patent lists the title as “Methods and Compositions for Treating Excessive Sleepiness,” and the issue date as February 9, 2021.

16. The '976 patent lists the title as “Methods and Compositions for Treating Excessive Sleepiness,” and the issue date as March 30, 2021.

17. The '779 patent lists the title as “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function,” and the issue date as November 2, 2021.

18. The '133 patent lists the title as “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function,” and the issue date as March 9, 2021.

19. The '354 patent lists the title as “Compositions comprising (R)-2-amino-3-phenylpropyl carbamate and uses thereof,” and the issue date as January 24, 2023.

20. The '232 patent lists the title as “Methods and Compositions for Treating Excessive Sleepiness,” and the issue date as May 16, 2023.

21. Axsome purports and claims to be the owner of or exclusive licensee for, and to have the right to enforce, the Asserted Patents.

22. Hetero submitted Abbreviated New Drug Application (“ANDA”) No. 218654 to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Hetero’s proposed drug product containing solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base (“Hetero’s ANDA product”). Hetero submitted ANDA No. 218654 to the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '754 patent, the '976 patent, the '779 patent, the '133 patent, the '354 patent, and the '232 patent.

23. Hetero sent notice of this certification to Axsome on or about August 15, 2023 (“the Notice Letter”). On information and belief, and as Axsome alleges in its Complaint, Axsome received the Notice Letter.

24. On September 13, 2023, Axsome filed suit in this Judicial District against Hetero in connection with ANDA No. 218654 alleging infringement of the Asserted Patents.

25. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Hetero and Axsome having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the Asserted Patents, and as to Hetero’s right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero’s ANDA product.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,440,715)

26. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero’s Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

27. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’715 patent.

28. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero’s ANDA Product would infringe any valid or enforceable claim of the ’715 patent.

29. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '715 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,440,715)

30. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

31. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '715 patent are invalid.

32. Upon information and belief, the claims of the '715 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

33. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '715 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

34. The Court should declare that the claims of the '715 patent are invalid and/or unenforceable.

COUNT III

(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,195,151)

35. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

36. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '151 patent.

37. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '151 patent.

38. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '151 patent.

COUNT IV

(Declaratory Judgment of Invalidity of U.S. Patent No. 10,195,151)

39. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

40. Upon information and belief, the claims of the '151 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting,

and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

41. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '151 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

42. The Court should declare that the claims of the '151 patent are invalid and/or unenforceable.

COUNT V

(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,512,609)

43. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

44. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '609 patent.

45. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '609 patent.

46. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '609 patent.

COUNT VI
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,512,609)

47. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

48. Upon information and belief, the claims of the '609 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

49. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '609 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

50. The Court should declare that the claims of the '609 patent are invalid and/or unenforceable.

COUNT VII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,439,597)

51. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

52. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '597 patent.

53. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '597 patent.

54. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '597 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,439,597)

55. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

56. Upon information and belief, the claims of the '597 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

57. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '597 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without

limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

58. The Court should declare that the claims of the '597 patent are invalid and/or unenforceable.

COUNT IX

(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,912,754)

59. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

60. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '754 patent.

61. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '754 patent.

62. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '754 patent.

COUNT X

(Declaratory Judgment of Invalidity of U.S. Patent No. 10,912,754)

63. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

64. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '754 patent are invalid.

65. Upon information and belief, the claims of the '754 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

66. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '754 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

67. The Court should declare that the claims of the '754 patent are invalid and/or unenforceable.

COUNT XI
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,959,976)

68. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

69. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '976 patent.

70. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture,

use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '976 patent.

71. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '976 patent.

COUNT XII
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,959,976)

72. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

73. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '976 patent are invalid.

74. Upon information and belief, the claims of the '976 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

75. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '976 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

76. The Court should declare that the claims of the '976 patent are invalid and/or unenforceable.

COUNT XIII

(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,160,779)

77. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

78. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '779 patent.

79. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '779 patent.

80. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '779 patent.

COUNT XIV

(Declaratory Judgment of Invalidity of U.S. Patent No. 11,160,779)

81. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

82. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '779 patent are invalid.

83. Upon information and belief, the claims of the '779 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112,

and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

84. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '779 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

85. The Court should declare that the claims of the '779 patent are invalid and/or unenforceable.

COUNT XV
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,940,133)

86. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

87. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '133 patent.

88. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '133 patent.

89. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '133 patent.

COUNT XVI
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,940,133)

90. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

91. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '133 patent are invalid.

92. Upon information and belief, the claims of the '133 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

93. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '133 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

94. The Court should declare that the claims of the '133 patent are invalid and/or unenforceable.

COUNT XVII

(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,560,354)

95. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

96. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '354 patent.

97. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '354 patent.

98. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '354 patent.

COUNT XVIII

(Declaratory Judgment of Invalidity of U.S. Patent No. 11,560,354)

99. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

100. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '354 patent are invalid.

101. Upon information and belief, the claims of the '354 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112,

and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

102. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '354 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

103. The Court should declare that the claims of the '354 patent are invalid and/or unenforceable.

COUNT XIX
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,648,232)

104. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

105. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '232 patent.

106. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '232 patent.

107. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '232 patent.

COUNT XX
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,648,232)

108. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

109. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '232 patent are invalid.

110. Upon information and belief, the claims of the '232 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

111. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '232 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

112. The Court should declare that the claims of the '232 patent are invalid and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Hetero prays that the Court enter judgment in its favor and against Axsome as follows:

- A. Declaring that the filing of Hetero's ANDA No. 218654 has not and does not directly or indirectly infringe any valid claim of any of the Asserted Patents;
- B. Declaring that the commercial manufacture, use, offer to sell, sale within the United States, and/or importation into the United States of Hetero's solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base product described in ANDA No. 218654 does not, and would not, if marketed, directly or indirectly infringe any valid claim of any of the Asserted Patents;
- C. Declaring that the claims of the Asserted Patents are invalid;
- D. Ordering that judgment be entered in favor of Hetero and that Axsome's Complaint be dismissed with prejudice;
- E. Declaring this case exceptional and awarding Hetero its reasonable attorney fees and costs of defending this action and prosecuting their counterclaims under 35 U.S.C. § 285; and
- F. Awarding Hetero such other and further relief as this Court deems just and proper.

Dated: November 17, 2023

Of Counsel:

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Aaron S. Lukas (*pro hac vice* to be filed)
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Respectfully submitted,

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: November 17, 2023

s/ Kaan Ekiner
Kaan Ekiner

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants/Counterclaimants Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd., by its undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: November 17, 2023

s/ Kaan Ekiner
Kaan Ekiner

CERTIFICATE OF SERVICE

I, Kaan Ekiner, hereby certify that on November 17, 2023, a true and correct copy of the foregoing **DEFENDANTS HETERO USA INC., HETERO LABS LIMITED UNIT-V, AND HETERO LABS LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT** was filed electronically with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

Dated: November 17, 2023

s/ Kaan Ekiner
Kaan Ekiner